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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09X273,230 03/18/99 CLELAND

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EXAMINER

HM12/1031

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BANSAL, G

ART UNIT

PAPER NUMBER

1642

7

DATE MAILED:

10/31/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/273230

Applicant(s)

Cleveland et al

Examiner

gBansal

Group Art Unit

1642

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. *(3 weeks)*

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 8/29/00
- ☐ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 42-49 is/are pending in the application.
- Of the above claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 42-49 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) _____.
- ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____ ☐ Interview Summary, PTO-413
- ☐ Notice of Reference(s) Cited, PTO-892 ☐ Notice of Informal Patent Application, PTO-152
- ☒ Notice of Draftsperson's Patent Drawing Review, PTO-948 ☐ Other _____

Office Action Summary

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DETAILED ACTION

1. Applicant's election of claims 42-49 without traverse filed 8/29/00 (Paper No: 6/B) is acknowledged. Applicant's amendment is herewith acknowledged. Accordingly, claims 37-41, 50 have been canceled without prejudice. Claims 42-49 are being examined.

Claim Rejections - 35 U.S.C. § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 42-49 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to the invention commensurate in scope with these claims. The claims are drawn to a method of treatment of patients having carcinoma as outlined above. The claims are also directed to a method of treating any patient having any carcinoma by administering an antibody against the HER2 receptor. There is no teaching disclosed in the specification of treating or inhibiting the growth of tumpr cells. The specification discloses methods of making different formulations of an antiHER-2 antibody and an anti IgE antibody. There are a number of examples to support the various formulations for providing stability to a preparation of antibodies, diggeent stabilizing agents used, different reconstituon experiments, but no guidance as to how to set about treating a mammal with a cancer overexpression of HER2R. One of skill in the art would be forced into undue experimentation to practice the claime invention becuase the specification does not provide a teaching as to what properties of an anti HER2 Mab would have

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therapeutic efficacy, whether in the form a conjugate or alone, how to set about obtaining a therapeutically effective antibody. The disclosure has no connection with the claimed subject matter, but merely provides methods and guidance to produce an antibody formulation. Claims drawn to treating a cancer are not enabled by the disclosure. An effective therapeutic protocol for the treatment or prevention of the formation of a tumor is subject to a number of factors which enter the picture beyond simply the specific binding of an antibody to the tumor cell line or the derived antigen. Demonstrating tumor antigen specificity in vitro cannot alone support the predictability of the method for prevention of or treating said tumor growth through administration of either the antibody. The establishment and growth of a tumor is subject to variables beyond antigen specificity. The ability of a host to suppress and thereby prevent the tumor from establishing itself will vary depending upon factors such as the condition of the host, the type of tumor (rapidly proliferating or slowly proliferating) and the tumor burden. No guidance is provided for all of these points as set forth above.

4. No claim is allowed

5. Papers related to this application may be submitted to Group 1640 by facsimile transmission. Papers should be faxed to Group 1640 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 308-4242 or (703) 305-3014.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Geetha P. Bansal whose telephone number is (703) 305-3955. The examiner can normally be reached on Mondays to Thursdays from 7:00am to 4:30pm and alternate Fridays from 7:00am to 3:30pm. A message may be left on the examiner's voice mail service.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Anthony Caputa, can be reached on (703) 308-3995.

7. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

September 26, 2000.


GEETHA P. BANSAL
PRIMARY EXAMINER